EXHIBIT 8

to

PAUL D. BRACHMAN DECLARATION IN SUPPORT OF DEFENDANT'S TRIAL BRIEF

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PANAMA CITY DIVISION

RESTORE ROBOTICS, LLC, RESTORE ROBOTICS REPAIRS, LLC, and CLIF PARKER ROBOTICS, LLC, Plaintiffs, v. INTUITIVE SURGICAL, INC., Defendant.	Case No: 5:19-CV-55/TKW-MJF Pensacola, Florida January 13, 2023
INTUITIVE SURGICAL, INC., Counterclaimant, v. RESTORE ROBOTICS, LLC, RESTORE ROBOTICS REPAIRS, LLC, and CLIF PARKER ROBOTICS, LLC, Counterclaim Defendants.	2:02 p.m.

TRANSCRIPT OF PRETRIAL CONFERENCE
BEFORE THE HONORABLE T. KENT WETHERELL, II
UNITED STATES DISTRICT JUDGE
(Pages 1 through 108)

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P R O C E E D I N G S

(Call to Order of the Court.)

THE COURT: Y'all be seated, please.

All right. This is Case Number 5:19cv55, Restore Robotics v. Intuitive Surgical.

Why don't we begin with appearances, please.

MR. BERHOLD: Good afternoon, Your Honor. Jeff Berhold for plaintiffs.

MR. HARRISON: William Harrison for the plaintiffs.

MR. RUBY: Good afternoon, Your Honor. My name is Allen Ruby for the defendant.

MR. LAZEROW: Good afternoon, Your Honor. Andrew Lazerow for defendant, Intuitive Surgical.

MS. WINNER: Good afternoon, Your Honor. Sonya Winner for defendant, Intuitive.

MS. LENT: Good afternoon. Karen Lent for Intuitive.

MR. MENITOVE: Good afternoon. Mike Menitove for Intuitive.

MR. MCGEE: Good afternoon, Judge. David McGee for Intuitive Surgical.

THE COURT: All right. Good afternoon to everybody.

We've got a fair amount to cover today, and we've got as much time as we need to do it.

I guess let me -- let's kind of begin out of order. I have one of our marshals up here because one of the issues the

saying, "We had this series of correspondence" -- excuse me -- "and the FDA quite recently said, when you do this, it's remanufacturing."

And the jury can decide, is that what Restore was doing and does that require 510(k) clearance or not?

But we thought that she stopped short of the line that you drew, which was to say, is 510(k) clearance required? She did not say that.

THE COURT: Well, I'm reading the last sentence of her updated report where she says, "The consistency of these communications, as well as the creation of a new product code, demonstrates that the FDA has a clear and distinct policy that any increase in the number of uses to EndoWrist instruments beyond which they were originally cleared requires a 510(k) submission, review, and a clearance determination of the 510(k)."

MS. LENT: And that's her explaining what that QSM code means. Again, I think that that's consistent with your order. She's not saying, "Restore needed 510(k) clearance." She's saying, "The FDA has determined that extending the number of uses in these EndoWrist instruments is remanufacturing. Under the FDA regulations, remanufacturing requires 510(k) clearance." I think that's as far as she'd go.

THE COURT: I guess, to me, that -- the conclusion she's drawing there is, if not over the line I thought I drew,

it's further than I think she should be permitted to go. I don't have a problem with her describing that -- what I just said, that on the newfangled Xi version, Intuitive submitted a request, or whatever they did, and the FDA sent it back and said they have to go through 510. I mean, that fact could be evidence from which the jury could infer that the FDA has decided that it's required.

Similarly with the QSM code, the fact that they have created a new code could be evidence from which the jury could infer that 510 clearance is required.

Finally, this whole run-it-up-the-chain process, again, is evidence from which the jury could infer that that statement from the team lead is wrong, right -- I don't remember exactly what it was.

But I think all of those facts, I don't have a problem with her coming in and telling the jury what happened in the context in which it happened, but taking that next step, which I read that last sentence to do, to say, "Jury, I'm now telling you what -- the answer to the question, and you've got an instruction in there on it. I'm telling you what the answer to that question is," I have a little bit of concern with that, because while it's not specifically saying Restore needed one, for all intents and purposes, it is.

And so maybe I'm drawing too fine of a distinction in my mind, but that's kind of how I see it. Because ultimately,

what I anticipated in this whole thing was that we would do something very similar to what you've proposed -- y'all had proposed, or somebody's proposed in their instructions, which is to say, "The FDA regulates medical devices. Some devices that are comparable to other devices can be approved through or cleared through the 510(k) process. Devices that are remanufactured can't. A remanufactured device is this, that, or the other."

And essentially, that's kind of -- we tell them what the law is in the remanufacturing context. We've got Ms. Rosecrans and whatever they're going to bring forward, lay witnesses or experts, to articulate what -- how the process works and what their particular devices are and where they fit in, and the jury then will ultimately have to make that determination, is how I see it. Maybe I'm just completely missing something, or the hour has gotten to me, but...

MS. LENT: Well, Your Honor, your prior ruling said that she couldn't espouse a personal interpretation that differed from the FDA's public interpretations, and these are the FDA's public interpretations which specifically says to Iconocare, "When you extend the number of uses of these EndoWrist instruments, that is remanufacturing." And that --

THE COURT: And again, I think she can come in and explain what the significance of this new QSM code is and the fact that it was given to the folks that they now own, and --

but again, I think there's still a line that gets her to the point of instructing the jury about the law, and I'm not sure that's her job.

MS. LENT: I'm not sure where that line begins and ends. Because --

THE COURT: Right.

MS. LENT: -- the documents say, literally, when you extend the usage, the use -- the number of uses in these instruments, it is remanufacturing. So why couldn't she say that?

THE COURT: Mr. Berhold.

MR. BERHOLD: I'm not familiar with that quote actually. One, I agree with the Court that the line was drawn in the first place. I agree that she's gone over the line. I think it's important to say -- I mean, that's the whole debate, right, is the FDA itself has never -- even the FDA, after four years, has never taken a clearer position.

They're saying, "We can interpret from a product code this," or "We can interpret from the boilerplate from a 510(k) that." So, so long as the FDA hasn't made a decision on that point that a 510(k) is required, we don't think it's -- if that was the case, that would be evidence in and of itself. It would speak for itself.

In the meantime, it's not Ms. Rosecrans' position to say one way or the other. In fact, we know the FDA has never

stopped anyone from repairing these instruments. That's the issue of fact.

THE COURT: And their argument on that was they told -- I don't know if it was you or Rebotix -- to stop, definitively, through -- or at least some email, whatever that was. I remember that email in the record saying, "We think this is remanufacturing. You need to submit a 510(k)." So I guess it didn't tell you to stop, but it sent the message that you need to go through their process.

And the response back was, "We're doing other things right now, so put a pin in it."

And so semantics, maybe, but it may be significant. I mean, they're going to argue that their last definitive statement was telling y'all that you needed one. You're going to argue that the last definitive statement was this team lead saying, "We haven't decided." And they're going to then say, "Well, maybe they haven't specifically decided, but the team lead has said nobody's run that up the flagpole; and that, thus, is the last statement, coupled with the fact that they made us go get one, coupled with the fact that they created this new product code."

Again, to me, it's all argument for counsel to make in closing or wherever. And it's Ms. Rosecrans' function to explain the process and what happened, not to then make what I think is a legal assessment, which I read her last thing -- last

sentence of that report to be, ipso facto, 510(k) is required. And I don't think -- I think you're right. I think it is required. I think the FDA is sending the message that it's required, but they haven't said it, and I'm not going to say it in the first instance. And I know you want me to, and we've had that debate. We're past that.

But the fact remains, I don't -- and because we're simply giving the jury in the instruction -- maybe it's not going to be these exact words, I haven't found it, but page 99, your FDA clearance, that was, in essence, what I expect -- and I know we'll have argument on it at the appropriate time, but that was the essence of what I expected to instruct the jury on. There's a requirement. It depends on whether you're remanufacturing or not. They will have heard evidence, and they can decide using Ms. Rosecrans' assessment of things, the plaintiff's assessment of things whether that's remanufacturing or not and make a determination.

So all that being said, I'm -- the ultimate ruling is that I'm denying the motion, the Daubert motion or whatever it was called, in large part with that clarification that Ms. Rosecrans cannot provide that ultimate opinion that she seems to want to provide, that FDA has now definitively determined that 510 clearance is required for this type of activity.

So she can take the jury up to that point, and it will

be up to the jury to make that last inference, if that's the inference they want to make. Well, in the order that comes out of today, we'll try to articulate that in a slightly better way.

But is there any confusion on that, or do you get the gist of what I'm saying?

MR. BERHOLD: Restore gets the gist of it.

THE COURT: Ms. Lent?

MS. LENT: I understand what you're saying.

THE COURT: Okay. All right. We'll try to articulate that, and the same rule will apply that in the event that we don't articulate it in a way that makes sense or creates more problems or goes beyond what you think we said and what you think you understand, we'll entertain clarification, but certainly not reargument because I think we've hashed and rehashed pretty well.

So I think we've gotten to most everything.

Mr. Ruby, you had mentioned something about jury instructions, and I know we're not going to go through the instructions as a whole.

One thing I did want to specifically speak to -- and I know the parties just gave me -- on a lot of the preliminary instructions, just gave them to me not knowing whether we're going to use depositions or interrogatories and admissions and things like that, but we've got the language if we need it.

Jury questions, my understanding is that there's no